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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/646,898 | 08/22/2003 | Joar Opheim | 012098-0012-999/NN009 | 1343 |
| 84258 | 7590 | 09/21/2011 | EXAMINER | |
| JONES DAY (for Nordic Naturals) 222 EAST 41ST. STREET NEW YORK, NY 10017-6702 | | | GHALI, ISIS A D | |
| ART UNIT | PAPER NUMBER | | | |
| | | | 1611 | |
| MAIL DATE | DELIVERY MODE | | | |
| 09/21/2011 | | | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|-------------------------------|-------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/646,898 | OPHEIM, JOAR |
| | Examiner Isis Ghali | Art Unit 1611 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 July 2011.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 1,2,5,8,17 and 18 is/are pending in the application.
- 5a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 1,2,5,8,17 and 18 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1448)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 07/01/2011.

Claims 1, 2, 5, 8, 17 and 18 are pending and included in the prosecution.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 5, 8, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Soft Gelatin Capsules" by J. P. Stanley (IDS filed 01/21/2009) in view of Hutchison et al. (US 5,817,323 of record).

Applicant Claims

Applicant's claim 1 is directed a flavored capsule encapsulating a dose of fish oil, comprising a flavored capsule and a dose of fish oil, wherein the flavored capsule comprises: a) a forming agent chosen from the group consisting of gelatin and vegetable starch; b) a capsule softener; c) water; and d) a water soluble flavoring; wherein said capsule softener is present in the range of about 10% to about 35%, the water is present in the range of about 6% to about 10%, the water soluble flavoring is present in a concentration of about 1.5%, and the water soluble flavoring is a lemon flavor, and wherein the dose of fish oil is encapsulated by the flavored capsule.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Stanley teaches gelatin capsules comprising in its shell gelatin, plasticizers, water and flavor. Plasticizer is glycerin or sorbitol (page 400; right column) that are claimed by applicant as softener. Stanley teaches essential oil up to 2.0%, and/or water-soluble flavoring such as sucrose up to 5%, which range encompasses the claimed

range of about 1.5% (table 13-3 in left column in page 401). The capsules after drying will contain 6-10% water in the shell (page 407, right column). Regarding the claimed amount of softener (plasticizer), Stanley discloses flavored gelatin capsules comprising in the shell 400 mg of dry gelatin and 200 mg of dry glycerin (softener) per gram along with 62 mg of water (paragraph bridging page 408 and 409). The percent of glycerin is calculated by dividing 200 mg by 662 mg total weight to yield a value of 30.2%. This value falls within the required range of 10% to 35% in claim 1.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Stanley teaches up to 2% essential oil and up to 5% water soluble sucrose in the capsule shell, however the reference does not explicitly teach water soluble lemon flavor as instantly claimed by claim 1. Stanley does not teach vegetable starch in the capsule as claimed by claim 18.

Hutchinson teaches soft gelatin capsule comprising flavoring agent in the shell and contents of the capsule. Flavors that can be present in the content or shell of the capsule are selected from essential oils and fruit flavor or combinations thereof (col.5, lines 43-49). Examples C9 and C10 showed lemon flavor, as instantly claimed. The capsule shell may comprise potato starch which reads on vegetable starch (col.4, lines 60-63). Fruit flavors are expected to be water-soluble since compounds and their properties are inseparable.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Therefore, the prior art recognized gelatin capsules with flavored shell, and also recognized the equivalency and combination of essential oil flavors and fruit flavors in the capsule content and shell as well.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gelatin capsule to deliver fish oil comprising shell containing gelatin, plasticizer, up to 5% water soluble sucrose and/or up to 2% of essential oil flavor and 6-10% water as taught by Stanley, and replace the sucrose and/or the essential oil in the shell with the fruit flavor taught by Hutchison, especially lemon flavor. One would have been motivated to do so because Hutchison teaches lemon flavor as preferred flavor as evident by its exemplification, and because Hutchison teaches the equivalency between fruit flavors and essential oils, or their combination, as flavoring agent used in the shell as well in the contents of gelatin capsule. One would have reasonably expected formulating gelatin capsule to deliver fish oil comprising shell containing gelatin, plasticizer, up to 2% of lemon flavor and 6-10% water that imparts palatable taste to unpleasant fish oil content of the capsule to successfully improve patient compliance.

Regarding claims 8, it is known in the art to flavor the contents of the gelatin capsule using essential oils as taught by Hutchison, and one having ordinary skill in the art at the time of the invention would have flavored the oily material encapsulated in the

gelatin capsule with oily flavor to ensure its solubility and stability in the capsule contents.

Regarding claim 18, vegetable starch was known at the time of the invention to be used in capsule shell as taught by Hutchison.

Regarding the claimed amounts of plasticizer (softener) and water soluble flavor, the amount taught by Stanley overlaps with the claimed amount. Therefore, the amounts and corresponding ratio overlaps with the instant claims. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ 2d 1934 (Fed. Cir. 1990). Determining the optimal concentration of plasticizer and water-soluble flavoring is deemed to be routine and well within the skill of the artisan.

MPEP 2144.05 reads in-part: "Generally, difference in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentrations or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454,456, 105 USPQ 223, 235 (CCPS 1955)."

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

4. Applicant's arguments filed 07/01/2011 have been fully considered but they are not persuasive.

The examiner believes that the present invention as a whole as defined by the claims would have been *prima facie* obvious in the meaning of USC 103 (a) in view of the cited references. Stanley teaches the claimed product except for the specific lemon flavor which is taught by Hutchison.

Applicant argues that evidence of secondary considerations previously presented in Applicant's August 2010 Office Action response is almost exactly commensurate in scope with the amended claims, and the evidence of secondary consideration presented in the previously presented declarations sufficiently rebut any possible conclusion of obviousness over the cited references. Applicant argues that claims 1, 2, 5, 8, 17, 18 do not encompass "any ingredients and doses of the content of the capsule other than fish oil and flavor" as alleged by the Examiner. Rather, the claims are directed to a flavored capsule which encapsulates a dose of fish oil. The products described in the previously submitted declarations fall within the scope of the claims as amended. The flavored gelatin capsules referred to in the sales figures in the Declaration of Opheim of September 21, 2006 contain "gelatin, capsule softener present in an amount of approximately 30-32%, water present in an amount of approximately 8% and a water soluble flavoring (typically a lemon flavoring) present in an amount of approximately 1.5%." See *Id.* at ¶ 4. Declaration of Opheim of January 16, 2009, ¶ 3.

The formulations of fish oil in the Declaration of Cooperman of March 29, 2007 are encapsulated in capsules that contain "gelatin, capsule softener present in an amount of approximately 32%, water present in an amount of approximately 8% and a water soluble flavoring (a lemon flavoring) present in an amount of approximately 1.5%. In the Declaration of Cooperman of March 29, 2007 at ¶ 5, 6, Declarant notes that increased patient compliance seen with Nordic Naturals' products is "to a large extent due to flavoring added to [lemon-flavored] shells." The secondary evidence also demonstrates that Nordic Naturals' products having lemon flavored gelatin shells sold better than products that did not contain such shells, including unflavored gel capsules, flavored liquids and non-flavored liquids. See Declarations of Opheim of September 21, 2006, January 16, 2009, and August 16, 2010. Nordic Naturals sold approximately twenty five more times the number of units of flavored gelatin capsules fish oil supplements, which include lemon flavored capsules fish oil supplements, compared to unflavored counterpart. The pleasant smell of the flavored gelatin capsules, however, encouraged people to taste the supplements and most found eating the capsules to be a surprisingly pleasant experience. See Id. at 2-3, ¶ 5, 6 and 8. Despite initial skepticism in the industry and with consumers alike, Nordic Naturals flavored gelatin capsule fish oil supplements, including the claimed subject matter, have gained commercial success. Further, the evidence provided demonstrates that the lemon flavored gelatin shells improved palatability and patient compliance even with high concentration of fish oils, suggesting that the lemon flavored gelatin shells could improve the palatability of fish oils at lower concentrations as well. See Declaration of Cooperman of March 29, 2007.

In response, it is noticed that the objective evidences are insufficient to overcome the rejection of the claims based upon U.S.C. 103 (a) as set forth in this office action because: there was no showing that the objective evidence of nonobviousness as well as commercial success are commensurate in scope with the claims. See MPEP § 716. The scope of the claims is broad covering any amount of fish oil in the content of the capsule and any oil flavor in the content of the capsule. **It is not clear if the success was a result of the small amount of flavor in the capsule shell, or it was due to the amount of fish oil and flavor in the capsule content masking the fish oil odor and smell.** Applicants stated that "The secondary evidence also demonstrates that Nordic Naturals' **products having lemon flavored gelatin shells sold better than products that did not contain such shells, including unflavored gel capsules, flavored liquids and non-flavored liquids.**" This is not unexpected from capsules containing flavors versus capsules not containing flavors, and therefore cannot rebut *prima facie* obviousness. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness of the claims at issue." *In re Corkhill*, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). *In Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967).

The declarations include statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716. Providing samples to consumers is an advertising process and would have increased the sale rates.

The examiner agrees that applicant has presented evidence demonstrating the non-obviousness of flavored gelatin capsules containing fish oil as long-felt need in the art, skepticism in the art, commercial success, and copying by others. However, claims 1, 2, 5, 8, 17, 18 encompass many other ingredients and doses of the content of the capsule other than fish oil and flavor that would have role in success of the product. The claimed oil flavor in the content of the capsule is unlimited. Therefore, the evidence of non-obviousness is not commensurate with the scope of the claims. It is not demonstrated that the small amount of the lemon flavor in the shell was the reason of the commercial success of "Nordic Naturals' flavored fish oil gelatin capsules"; it could be the flavored content because it is the fish oil content that caused the unpleasant experience to the consumer and the oil flavor in the content could be the reason for the improvement of the taste and smell. Declaration filed august 16, 2010 in ¶ 6, specify strawberry flavor having high concentration of fish oil. The present claims are not directed to strawberry or any concentration of fish oil.

Further, the present invention as a whole is taught by the combination of the cited prior art. Gelatin capsules containing fish oils are known, flavored shell was

known, specific flavors and small amounts of flavor in the shell all were known at the time of the invention.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611